principles and conjure up several designs that would work. I can't patent every possible design.

I am seeking patent protection for the use of very pliable tubing in cannulas that have any nosepiece that will allow it. This is an idea that is contrary to common wisdom, it is not likely that one skilled in the industry would expect success using this type of tubing and it has escaped the minds of thousands of engineers and inventors for the past fifty years. I am also seeking protection for the use of my tubing, or tubing with similar properties, for use as extension tubing or the larger diameter main tubing that connects to the oxygen source. I found that this type of tubing does not form into knots as readily as standard PVC. This was not foreseen by any means and I still can't be certain my understanding is correct. Nonetheless, it does work well.

I am also seeking protection for the design of my nosepiece. It is not the only design that will work with my tubing but it is better than any other on the market. The nosepiece came before the tubing so the first cannulas I made used the vee-shaped nosepiece with regular tubing. These were markedly more comfortable than others so I wish to claim the nosepiece with or without the special tubing.

Points listed in the Office Action

Claim 1-3 rejection- Salter patent describes arcuate angle

As a first-time patent applicant I modified the language in Salter's patent to suit my own device. The Salter cannula (nosepiece) is straight in the middle with arms on both sides that bend at an angle. The words in the patent are "The main body portion has a horizontal axis extending along its length with an elbow formed at each end". This was a major advance in cannulas and is one of the reasons the Salter cannula is widely used. However, it is important to note that it has a straight central section that is wider than the spacing between the prongs. My cannula has no straight central section. It looks like a vee and the shape is critical in that it puts much of the weight below the point where tubing joins the arms. The center of the vee is also a low point that clears the underside of the nose. This is not an incidental point; it is a fundamental reason for the success of this invention. The words are almost identical but differ in this aspect.

Claim 2 rejection-Salter figures show tip with tapering wall thickness

The Salter patent clearly shows the material tapering to a sharp point. This a bit of artistic license as the parts made by Salter are rather blunt at the end. In practice, molding parts with a sufficiently thick body and tips as thin as described in my application is extremely difficult to do. Much time was spent experimenting with mold materials and process variables to be able to mold a part with tips as thin as Saran Wrap. It is not difficult to make thin sections with dip molding (condoms, rubber gloves) but it is very difficult to quickly taper from thick to very thin. The method I developed is an invention on its own. I did all this because I found that below a certain thickness the feeling of something in the nose goes away. It has to be pretty thin, much thinner than any other cannula. Neither the Salter patent, nor any other cannula patent describes the

thickness of the tips in detail. The idea that feeling goes away below a certain thickness is not mentioned in journals, patents or in any products in the marketplace. It makes it much more comfortable and costs no more to produce so it would certainly be included in a patent if someone was aware of it. According to MPEP 2125, the drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art. There is nothing in the drawing that would suggest that feeling goes away below a certain thickness. Making a nosepiece like the one depicted would not have the characteristics claimed in my application. It also says when the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.

Claim 3 rejection-figure in Salter patent depicts inward curving prongs

Again this is artistic license. The cannulas Salter manufactures, nor any other brand, curve inward because it is less amenable to automated production. My application describes in detail why the curvature is important and provides dimensions. No patent makes any reference to the importance of the curve and nobody manufactures a cannula with this feature so it can be said that the importance is not understood by those skilled in the art. Also there is no indication the drawings are to scale.

Obviousness rejections

Claims were rejected because a person skilled in the art would have been able to come up with an invention like mine based on information published in patents and knowledge of the industry. I will talk of the large numbers of patents that deal with the very problems mine solves but it a more complex manner and with lesser success. I will also show that common knowledge teaches away from the use of very flexible tubing and a skilled person would not expect success. I have more supporting information later.

Claims 4 and 10-10% tensile modulus of tubing

The rejection suggests one skilled in the art would know enough to choose flexible material to prevent damage in the nasalabial area. Claims 4 and 10 concern material for the tubing for which the 10% modulus is a measure of the "rubbery feel" that gives this tubing such a high degree of flexibility. It is this flexibility that makes the cannula so much more comfortable to wear. The referenced Salter patent does not deal with tubing properties at all. The flexible material in that patent refers to the nosepiece.

Claims 6 and 12-compression set less than 45%

Compression set is a standard specification given for flexible materials and is an indication of how a piece of tubing maintains a bent shape after the bending force is removed. One of the biggest problems with cannula tubing is that it has "memory" and takes a long time, if ever, for curls etc. to relax and straighten out. The tubing has to be pulled tight against the face to straighten the tubing and that causes sores. The tubing I use has almost no memory and this is quite important for making a cannula comfortable. The rejection letter points to a line in Salter's patent that teaches a flexible tube but the

patent actually teaches a flexible material for the nasal cannula which I am referring to as a nosepiece. Again, the Salter patent is about the nosepiece and not the tubing. Part of the misunderstanding is the meaning of the word "cannula". The whole thing with tubing, fittings and nosepiece is called a cannula and so is just the nosepiece. In the Salter patent the word cannula refers to the nosepiece only.

Claims 7 and 13 brittle temperature less than -40C

The low brittle temperature of my tubing is a measure of how flexible it is at low temperatures. Regular PVC becomes very stiff in cold temperatures and has been known to break. A cannula that remains flexible in cold weather is a distinct improvement over prior art and is critical to my invention. The Salter patent does not concern tubing properties at all.

Claims 9 and 15 high molecular weight (>100,000)

As before, the Salter patent refers to the material of the nosepiece only.

These all describe the critical properties of the tubing that make it work well in a cannula. These are all outside the specifications of commonly used tubing and also would not be considered to be of use by one skilled in the art. The 10% tensile modulus and compression set are measurements of the flexibility and rubber-like qualities of the tubing. The brittle temperature is a measure of the cold weather flexibility of the preferred tubing. The high molecular weight describes PVC material that can be used to create tubing with the desired properties needed for this invention.

Claims 5 and 11 40-75A hardness

The hardness specification is much lower than the hardness of tubing normally used. Softer generally means more flexible and that is important to my invention but is unsuitable for regular cannulas. The rejection of these claims is based on a patent that teaches flexible tubing with a hardness within the range I am claiming. I have included the reference and drawing

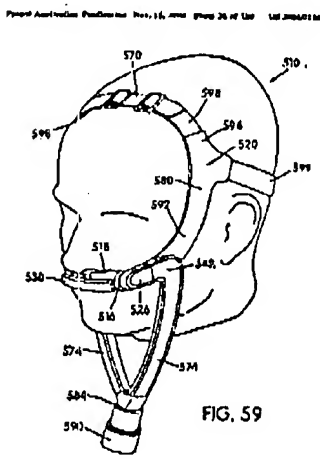

FIG. 59

[0304] The second connector portions 526 may be formed of silicone with a hardness of about 50-60 Shore A hardness. This hardness facilitates assembly, swiveling movement, and seal with the frame 516. However, the second connector portions 526 may be formed of any other suitable material and may have any suitable hardness.

The piece labeled 526 is not a piece of tubing. It is desirable for this part to be fairly rigid so it snaps together and will swivel. Silicone rubber is usually

quite soft. A 50-60 hardness is about as hard as silicone can be so this patent teaches away from mine. Thus it is not reasonable for a skilled person, already aware that soft tubing does not work for cannulas, to look at this non-tubing-like part that is supposed to be hard enough to swivel and from this get the idea to make tubing for a different application with properties directly opposite to both the patent and his own knowledge. My invention uses tubing to support the nosepiece while Gunaratnam has no tubing at all, relying instead on head gear and a rigid support arm. This is exactly what I don't want. If someone were motivated by this patent to put a harness on a Salter cannula, it would lead them father away from my invention.

Obviousness of softer tubing

Even though there is nothing in either the Salter or Gunaratnam patents that would lead someone to consider modifying tubing in a direction that is known not to work it may be possible that some patent out there somewhere may mention soft tubing in conjunction with comfort. But it would not be for use in a cannula. What may seem obvious to an average person in the street is a bad idea to someone skilled in the art and an attempt to build one just by changing tubing would be met with failure. Without the simultaneous knowledge of the nosepiece interaction, the idea or impetus to use soft tubing on a cannula is worthless and would not lead to success. Establishing some reference about soft tubing does not render my invention obvious.

The problems solved by my cannula have been around a long time and a lot of effort has gone into solving these problems as evidenced by the large number of patents. Enough time has passed for obviousness to have surfaced. The idea I came up with does not depend on new technology that I was privy to first nor does it involve some exotic materials that could not be used economically nor is it difficult to build. My idea is a simple solution that is very effective and the fact that no one has done it is proof that it is not obvious.

This invention is not one that someone could sit down, do some calculations and come up with a cannula that works as well as mine. I used tubing with properties that were known to be unsuitable and had to invent a nosepiece to make it work. The idea to use soft tubing is worthless without the right nosepiece and the nosepiece I invented just happened to be right. The result is a cannula that is much more comfortable than anything else available. The flexibility tends to multiply the improvements in many unforeseen ways. For instance the flexible tubing doesn't distort the nosepiece in the package so the nosepiece can be made thinner and lighter. The elastic properties allow the user to pull the nosepiece away from the face to blow one's nose and it snaps back as opposed to having to loosen the tubing enough to pull it away. Because the tubing isn't pulled tight it doesn't need to be thick to prevent flattening. Thus the tubing can be made with thinner walls, reducing both cost and weight. The less everything weighs the easier it is to stay in place. The improvement in comfort is hugely out of proportion to the relatively minor changes that were made.

There is nothing in literature or patents that would lead a person skilled in the arts to any single part of this invention let alone to put together all that was needed to make this invention work. Many people have given much effort and thought over many years attempting to design solutions for just one of the multitude of problems caused by cannulas and my invention solves all of them. As simple as it is, there is no part of my invention that is obvious and the proof is that several generations of inventors have tried to solve problems that still exist.

When determining obviousness one must consider the invention as a whole. My invention involves flexible tubing in combination with a particular nosepiece. A reference that mentions tubing hardness is not sufficient on its own to make a determination of obviousness.

To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. No such line of reasoning was presented.

My idea is simple to understand and simple to implement and will work in more ways than it won't. It is somewhat difficult to show that an idea so simple is not an obvious one. I think the most commanding evidence to support nonobviousness is to point to the long history of the devices, the millions of people who have manufactured, designed, sold and used cannulas and yet no one has put together, or even come close to putting together the pieces to the puzzle. It is not seen in the marketplace or known in the industry and is not seen in cannula patents. The problems my idea solves have been the subject of a wide variety of inventions. (I have included pictures of examples at the end.)

Another powerful argument for nonobviousness is if the idea is an effective solution for a recognized problem. If it is an invention that satisfies a great demand, is successful and far above the rest and there is no hint anywhere than anyone else knows it, that passes the test for an original invention.

It is everything an invention should be. It is inexpensive, can be mass produced, easy to implement with little change to production methods and equipment, satisfies large demand in growing market and no one else has done anything similar.

Paul Thompson 07/08/07